

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1, 5-7, 9, 14-15 and 29 are pending in this application. Claim 1 is amended and claim 29 has been newly added. Support for the amendment to claim 1 and new claim 29 can be found in original claim 3 and Example D of the specification as filed. Claims 3, 22 and 24-25 have been cancelled. Claims 1 and 29 are the independent claims.

Furthermore, upon review of the enclosed Amendment, Applicants respectfully request that the Examiner contact the undersigned to discuss the Applicants' reasoning and/or possible claim amendments that may place the application in condition for allowance.

Information Disclosure Statement

The Examiner states that Applicant's IDS, filed on September 1, 2009, is acknowledged and considered except for JP 08-504088 because the Abstract is not in English. Applicants respectfully disagree.

As can be seen on the PAIR retrieval system, the JP 08-504088 reference filed on July 25, 2008 was submitted with an English abstract of the English equivalent of the Japanese reference, US Patent No. 5,614,373. Applicants are providing the aforementioned English equivalent, which is listed in the enclosed PTO-1449. Applicants respectfully request that the next U.S.P.T.O. communication include an initialed copy of the attached PTO-1449 form indicating that the JP 08-504088 reference has been considered.

Claim Objections

Claims 1, 3, 5, 6, 22, 24 and 25 have been objected to for informalities. Applicants have amended claim 1 accordingly and cancelled duplicate claims 22, 24 and 25. Therefore, withdrawal of the objections to the claims is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 5-7, 9, 14, 15, 22, 24 and 25 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants submit that claim 1 as amended accordingly. The Applicants, therefore, respectfully request that the rejection to claims 1, 3, 5-7, 9, 14, 15, 22, 24 and 25 under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-3, 5-9, 14-16, 22, 24 and 25 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

The Examiner points out in the FOA that the term "substance carrier" is equivalent to "drug" (see Point 15), presumably because the "substance" is described as being "for treating a disease." In view of this, Applicants have amended claim 1.

Furthermore, Applicants respectfully submit that the Examiner does not seem to sufficiently take into consideration the previously submitted Declarations as the term "substance carrier" has been clearly distinguished from the term "drug". As additional evidence, Applicants attach a Declaration executed by Mr. Kuroda, which gives additional evidence of how a "substance carrier" can be implemented. The "substance carrier" as recited in claim 1 includes (i) an

antibody which is displayed on the surface of the nanoparticles by binding to a ZZ tag and (ii) a substance to be transferred into a cell. The Declaration provides experimental data illustrating that the use of the ZZ tag enables various antibodies to be displayed on the surface of the nanoparticles. For example, Tables 1 and Figure 2 show that the ZZ domain can be bound to antibodies of various subclasses. The Declaration also illustrates that a substance (e.g., DNA) to be transferred into a cell can be transferred into desired cells which express respective antigens for the following three kinds of antibodies: an anti-nerve growth factor receptor antibody, an anti- sarcoglycon antibody, and an anti-CD3 antibody. Therefore, selecting an antibody based on its purpose is possible, and thus, is not limited by the kind of antibody.

As described above, the claims are characterized by the ability to display various antibodies with use of the ZZ tag. Therefore, Applicants respectfully submit that there is no need to limit the kind of substance to be transferred into a cell. In addition, while the experimental data of the Declaration uses DNA as an example of the substance to be transferred into a cell, a previously submitted Declaration illustrates low-molecular-weight compounds as an example of the substance to be transferred into a cell, which clearly shows that various substances can be used as the substance to be transferred into a cell.

The Applicants, therefore, respectfully request that the rejection to claims 1-3, 5-9, 14-16, 22, 24 and 25 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. § 103

Kuroda in view of Ojala

Claims 1, 3, 5, 6, 7, 9, 14, 22, 24 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroda et al. (hereinafter "Kuroda"), WO 01/64930

(US 2003/0092069) in view of Ojala et al. (hereinafter "Ojala"), Biochem Biophys Res Commun., 2001; 284(3), 777-84, cited in previous Office Action. Applicants respectfully traverse this rejection for the reasons detailed below.

On page 11 of the Office Action, the Examiner again states that Kuroda teaches hollow nanoparticles composed of HBsAgL protein a biorecognition molecule to introduce a substance into the target cells or tissue, wherein the biorecognition molecule on the hollow nanoparticles is an antibody. Applicants respectfully disagree.

Applicants submit that the Examiner fails to point out (nor can Applicants find) where Kuroda, Ojala or the combination thereof teaches "a substance carrier comprising hollow nanoparticles of a particle-forming protein, the hollow nanoparticles displaying an antibody against a specific cell or specific tissue, and encapsulating a substance to be transferred into a cell, the antibody being displayed on the surface of the nanoparticles by binding to a ZZ tag fused with the particle-forming protein, and the particle-forming protein including a modified hepatitis B virus surface antigen large (L) protein" as recited in independent claim 1. In other words, the "substance carrier" as recited in claim 1 includes at least the following three elements: (i) a ZZ tag, (ii) a modified hepatitis B virus surface-antigen protein, and (iii) an antibody.

In contrast, "viral particles" disclosed in Ojala may include a "ZZ tag" and "gp64 (a viral envelope protein having the ability to form particles)", but do not include an antibody. Specifically, Ojala states on page 780, right column, the sixth line through the first line from the bottom, that after target cells were treated with antibodies, the cells were exposed to the ZZgp64-EGFP display virus. The technique disclosed in Ojala causes viral particles including a ZZ tag to bind to a target cell to which an antibody is bound, and thus, the "antibody" is not an

element of the "viral particles". A pretreatment of a target cell with an antibody is needed in the technique of Ojala, where no such treatment is required in the substance carrier as recited in claim 1. As such, neither Kuroda, Ojala nor the combination thereof teaches or suggests "a substance carrier comprising hollow nanoparticles of a particle-forming protein, the hollow nanoparticles displaying an antibody against a specific cell or specific tissue, the antibody being displayed on the surface of the nanoparticles by binding to a ZZ tag fused with the particle-forming protein" as recited in independent claim 1.

Furthermore, Applicants submit that the Examiner fails to point out (nor can Applicants find) where Kuroda, Ojala or the combination thereof teaches "encapsulating a substance to be transferred into a cell" as recited in independent claim 1. Kuroda teaches a biorecognition molecule being introduced thereto rather than encapsulating the cell as in independent claim 1. (See the claims). Ojala teaches a molecule binding to a cell surface molecule rather than encapsulating the cell as in independent claim 1. (See abstract). Therefore, neither Kuroda, Ojala nor the combination thereof can render obvious claim 1.

The Applicants, therefore, respectfully request that the rejection to Claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Claims 3, 5, 6, 7, 9, 14, 22, 24 and 25, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 1 and all claims dependent thereon.

Kuroda and Ojala in view of Rosenfeld

Claim 15 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroda and Ojala in view of Rosenfeld. Applicants respectfully traverse this rejection for the reasons detailed below.

Even assuming *arguendo* that Rosenfeld could be combined with Kuroda and Ojala (which Applicants do not admit), the Examiner has failed to show how Rosenfeld remedies the deficiencies of Kuroda and Ojala with respect to independent claim 1. Thus, claim 15 is patentable over Rosenfeld and Kuroda and Ojala for the reasons set forth above with respect to independent claim 1.

The Applicants, therefore, respectfully request that the rejection to Claim 15 under 35 U.S.C. § 103(a) be withdrawn.

Double Patenting Rejection

Claims 1-3, 5-9, 14-16, 22, 24 and 25 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 8 and 9 of co-pending application 11/987,476. Applicants respectfully traverse this rejection for the reasons detailed below.

Applicants respectfully submit that the nonstatutory obviousness-type double patenting rejection over claims 1-3, 6, 8 and 9 of U.S. Application No. 11/987,476 is moot, because U.S. Application No. 11/987,476 has been abandoned.

The Applicants, therefore, respectfully request that the double patenting rejection to Claims 1-3, 5-9, 14-16, 22, 24 and 25 be withdrawn.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

As discussed above, Applicants respectfully request that the Examiner contact the undersigned to discuss the Applicants' reasoning and/or possible claim amendments that may place the application in condition for allowance.

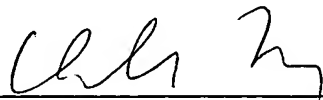
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By



Donald J. Daley, Reg. No. 34,313
P.O. Box 8910
Reston, Virginia 20195
(703) 668-8000

DJD/EGH:vrj

Attachment: PTO-1449 form
Declaration